

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

ATTY.'S DOCKET: AHARONI=2B

In re Application of:

Rina AHARONI et al.

Appln. No.: 09/831,629

Date Filed: May 11, 2001

For: PHARMACEUTICAL COMPOSTIONS)
COMPRISING SYNTYHETIC...

Art Unit: 1653

Bart Unit: 1653

Campaigner: D. Lukton

Confirmation D.C.

Confirmation No. 6949

Comprising Syntyhetic...

RESPONSE

Honorable Commissioner for Patents
U.S. Patent and Trademark Office
2011 South Clark Place
Customer Window, Mail Stop Non-Fee Amendment
Crystal Plaza Two, Lobby, Room 1B03
Arlington, Virginia 22202

Sir:

This communication is responsive to the Office Action of January 20, 2004, primarily in the nature of a written restriction requirement.

The examiner has required restriction under 35 U.S.C. §121 to one of the following six groups:

Group I, presently comprising claims 1 and 6-15, drawn to a composition and limited to G1;

Group II, presently comprising claims 1-5 and 15, drawn to a composition and limited to G2;

Group III, presently comprising claims 1-15, drawn to a composition and limited to G3;

Group IV, presently comprising claims 16 and 21-32, drawn to a method and limited to G1;

Group V, presently comprising claims 17-20 and 30-33, drawn to a method and limited to G2; and

Group VI, presently comprising claims 16-33, drawn to a method and limited to G3.

The subgenera G1, G2 and G3 are defined as follows:

- G1: The polymer consists of three and only three amino acids selected from Lys/Arg, Glu/Asp, Ala/Gly and Tyr/Trp;
- G2: The copolymer consists of four and only four amino acids as permitted by claim 1, i.e., the four amino acids are selected from the following ("D" or "L" isomers): KEAY, KDAY, KEGY, KEAW, KDGY, KDGW, KDAW, KEGW, REAY, RDAY, REG, REAW, RDGY, RDGW, RDAW, REGW;
- G3: the copolymer comprises or consists essentially of any peptide that is encompassed by claim 1, with the proviso the G1 and G2 are excluded.

The examiner states that Groups I-III and IV-VI are related as product and process of use. As such, the examiner has stated if any of Groups I-III is elected and allowable claims are found, the corresponding method-of-use claims will be rejoined.

Regardless of which group is elected, the examiner has further required the election of a single species for prosecution from each of the following groups:

- a. a specific copolymer, accompanied by a statement as to stereochemistry (i.e., "D" or "L") of each amino acid present in the copolymer and the composition;
- b. a molecular weight of a copolymer that must be present in the composition, noting that a range is not a specific molecular weight; and
- c. a statement as to whether the electrical charge of the copolymer is positive or negative.

Furthermore, if one of Groups IV-VI is elected, a second species is required to be elected, i.e., a specific organ or tissue, such as one of those recited in claim 33.

The restriction and election of species requirements are respectfully traversed. However, in order to be responsive, applicants provisionally elect with traverse Group II, drawn to a composition limited to subgenus G2, presently comprising claims 1-5 and 15, and the species of Copolymer 1 (Cop-1) having all L-amino acids, and an average MW of 7,000 daltons, and a net positive electrical charge.

Traversal of the restriction requirement is based on the fact that the instant application is a 371 national stage application and accordingly, is subject to PCT Unity of Invention

Rule 13, rather than U.S. restriction requirement practice under 35 U.S.C. §121. Therefore, with due respect to the examiner, the restriction requirement is improper.

The groups indicated by the examiner as being separate inventions all share a special technical feature, which is the generic copolymer recited as being contained in the pharmaceutical composition or being used in the method. The examiner has not cited any prior art reference that provides a prima facie showing of a lack of a special technical feature which can defeat the single general inventive concept under PCT Unity of Invention Rules linking the separate groups.

Reconsideration and withdrawal of the restriction requirement are therefore respectfully requested.

The requirement to elect a species, insofar as one limited to an average MW of a copolymer is concerned, is respectfully traversed. Traversal is due to the Cop-1 copolymer being a mixture of peptides of various lengths. This mixture of peptides cannot be limited to a particular MW. The examiner is respectfully directed to U.S. Patent 5,858,964, previously submitted by applicants as ref. AC in an IDS, which discloses the complexity of the mixture of peptides of various lengths that is the Cop-1 copolymer.

Reconsideration and withdrawal of the election of species requirement, insofar as the MW is concerned, is respectfully requested.

In the event that Group V (claims 17-20 and 30-33) is rejoined with the elected Group II and an election of species is still required for Group V, then applicants provisionally elect Kidney as the species of organ or tissue.

Reconsideration and examination of all of the claims now present in the case are earnestly solicited.

Respectfully submitted,

BROWDY AND NEIMARK, P.L.L.C. Attorneys for Applicant(s)

Ву

Allen C. Yun

Registration No. 37,971

ACY:pp

Telephone No.: (202) 628-5197 Facsimile No.: (202) 737-3528

G:\BN\Y\YEDA\aharoni5b\PTO\RESTresponse OA 1-20-04.doc